

REMARKS

In the Office Action, the Examiner rejects claims 1-2, 10-11 and 18 under 35 U.S.C. §102(e) as allegedly anticipated by Barbara-Guillem (US2003/0040104), hereinafter (Barbara-Guillem). The Examiner alleges that Barbara-Guillem discloses a cell culturing system that meets the each limitation of the rejected claims. This reference also forms the basis of the rejection of claims 3, 4, 6-9 and 17 under 35 U.S.C. §103; claims 5, 12 and 19 under 35 U.S.C. §103¹; 13, 14, 20 and 21 under 35 U.S.C. §103. Secondary references are raised in combination with Barbara-Guillem. The Examiner specifically rejects claims 3, 4, 6-9 and 17 under 35 U.S.C. §103 as allegedly unpatentable over Barbara-Guillem and Claus et al (CA 2303243). Claims 5, 12 and 19 are also rejected under 35 U.S.C. §103 as allegedly unpatentable over Claus et al. in view of Lerch et al. (WO 97/19754). Claims 13, 14, 20 and 21 have been rejected under 35 U.S.C. §103 as allegedly unpatentable over Barbara-Guillem in view of Pfaller (US6329195). Claims 15 and 16 have been deemed allowable if rewritten to overcome the rejection under 35 USC Sec. 112, 2nd paragraph as allegedly indefinite and to include all of the limitation of the base claim and any intervening claims.²

This response addresses each of the rejections of record. The claims are now believed to be in condition for allowance and favorable consideration of all pending claims is respectfully requested in view of the following remarks.

Claims 1-2, 10-11 and 18 have been rejected under 35 U.S.C. §102(e) as allegedly anticipated by Barbara-Guillem (US2003/0040104). The Examiner alleges that Barbara-Guillem discloses a cell culturing system that meets all the limitations of the

¹ The Examiner apparently failed to mention Barbara-Guillem in the first line of the rejection on page 8, but the body of the rejection is premised on Barbara-Guillem as the primary reference.

² There is no rejection under 35 U.S.C. §112, second paragraph. Clarification is requested.

claimed invention. It is axiomatic that for an anticipation rejection to stand the cited reference must disclose each and every element of the claimed invention within its four corners.

In the present case, the Barbara-Guillem reference does not teach, disclose or suggest the invention, as claimed. Without acceding to the propriety of the Examiner's rejection, applicants have amended claims 1 and 8-10 to recite (respectively) a cell culturing system, a cultured cell collating device and a cell culturing device that comprises, *inter alia*, an input unit that inputs identification information attached to the containers before and after transfer whenever cells are transferred to a different container, a unit to transfer cells between containers, and a memory unit that stores in memory identification information input from the input unit in mutual correlation. Nowhere does Barbara-Guillem teach, disclose or suggest a device as presently claimed. Support for the amendment to Claims 1 and 8-10 is found throughout the application and particularly at pages 36-37, with reference to Figure 12 which provides the skilled artisan with a sufficient depiction of the unit to transfer cells between containers. Given the explicit disclosure, the invention is capable of practice by the skilled artisan without any undue experimentation. Moreover, the specification provides a detailed mechanism including centrifuge 105, manipulators 106, 107, containers 108, refrigeration chamber 109, control device 111, pipette holders 112, pipettes 113, and work stages 114, 115 which encompasses a unit to transfer cells between containers. No new matter has been added.

Accordingly the rejection of claims 1-2, 10-11 and 18 under 35 U.S.C. §102(e) as allegedly anticipated by Barbara-Guillem is overcome and withdrawal thereof is respectfully requested.

Claims 3, 4, 6-9 and 17 have been rejected under 35 U.S.C. §103 as allegedly unpatentable over Barbara-Guillem in view of Claus et al. The Examiner concedes that Barbara-Guillem does not explicitly teach a rewriting unit, nor does it state that the identification information includes information relating to the steps in which each container is used, nor does it provide a collating unit, a reading unit or a system wherein judgment information for collating cultured cells is input from identification information.

The Examiner contends that Claus et al. ameliorates the deficiencies of the primary reference. Specifically, Claus et al (CA 2303243) allegedly disclose a unit that is capable of rewriting previously stored information already stored in memory (Claim 3) and a system wherein identification information includes information relating to the steps in which each container is used (Claim 4). Claus et al also allegedly disclose a system comprising a collating unit that collates cultured cells according to whether or not their correlation agrees with a correlation stored in the memory unit (Claim 6, 8 & 9). Claus et al. is alleged to disclose a system comprising a reading unit (Claim 7) and a memory unit capable of storing identification information of a culture container that contains a first specimen and the identification information of a culture container that contains another specimen cultured simultaneously to the first specimen in mutual correlation.

Applicants submit that Claus et al fails to remediate the multiple deficiencies of the primary reference Barbara-Guillem which has already been fully distinguished above. Claus et al. is directed to a fundamentally divergent device for registration of livestock. Claus et al., if anything, teaches away from a cell culturing system for obtaining, culturing and transplanting cells in a human patient, which is the

subject of the present invention. The specific features of the invention, as claimed, are not suggested by the combination of Barbara-Guillem and Claus et al.

Claims 5, 12, and 19 are rejected under 35 U.S.C. §103 as allegedly unpatentable over Claus et al. (this appears to be an error and should refer to Barbera-Guillem as mentioned in footnote 1, in view of Lerch et al. (WO 97/19754). Lerch et al. is asserted by the Examiner as allegedly providing the details that Barbara-Guillem lacks such as a system, wherein information in the hospital that is the origin of the incoming transport container is added to the incoming transport container (Claim 5), see page 8 of Lerch et al. The Examiner contends that the skilled artisan would have modified Barbera-Guillem to include sensors to control conditions in the biochamber (Claim 12) and further that it would have been achievable by the skilled artisan to modify Barbera-Guillem to include a sensor that detects internal culturing chamber information (as taught by Lerch et al). to provide feedback for each cell culture device within the automated cell management system.

Lerch is even further removed than Claus et al. (which teaches away from the claimed invention, as explained above). Lerch is directed to an article, a card, for collecting and transporting a whole blood sample. Picking and choosing specific features which reside in a blood test kit and applying them to an already deficient reference (Barbara-Guillem) represents a clear case of hindsight analysis which is not permitted under the patent law. Withdrawal of the rejection of Claims 5, 12 and 19 under 35 U.S.C. §103 is respectfully requested.

Claims 13, 14, 20 and 21 have been rejected under 35 U.S.C. §103 as allegedly unpatentable over Barbera-Guillem in view of Pfaller (US 6,329,195). The

Examiner admits that Barbera-Guillem does not disclose storing culture container identification information as claimed, but that Pfaller would be applied by the skilled artisan to modify the medium replacement unit of Barbera-Guillem with a unit as taught by Pfaller to provide adequate sample feedback during the cell culturing process. (Claim 13). Claim 14 is rejected based on the combination of Barbara-Guillem and Pfaller based on the disclosure in Pfaller of a medium replacement unit that replaces medium that has accumulated in a culture container (see Col. 2, lines 47-58). Regarding Claim 20, the Examiner concedes that Barbera-Guillem do not disclose medium replacement information including the date of medium replacement performed for that culture container, replaced medium, amount of growth factor and type of growth factor. The Examiner similarly has condeded that Barbera-Guillem do not disclose medium information including dissolved oxygen concentration and sugar content.

Curiously, the Examiner makes the unsubstantiated statement that it would have been obvious to modify Barbera-Guillem with a means for tracking medium replacement information given that cell culture requires essential nutrients and properties in order to maintain and support continued cell growth. Similarly, the Examiner contends, without any support, that it was obvious to modify Barbera-Guillem with a means for providing medium information specifically pertaining to the dissolved oxygen concentration and sugar content of the culture medium that is supplied.

In response, applicants submit that Barbara-Guillem in combination with Pfaller do not achieve, suggest, teach or predict the invention, as claimed. Notably, the cited references do not even consider a unit to transfer cells between containers, as claimed.

Accordingly, the rejection of Claims 13, 14, 20 and 21 under 35 U.S.C. §103 is overcome and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter I. Bernstein", with a long horizontal flourish extending to the right.

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